Remarks/Arguments

A. Status of the Claims

Claims 1, 3-4, and 16 are amended, and claims 13 and 18-24 are canceled. For instance, claim 1 is amended to delete the phrase "undergoing general anesthesia" and to recite "before general anesthesia is administered to the patient and before the patient presents symptoms of post-surgical vomiting." Claims 3 and 4 are amended to recite "also." Claim 16 is amended to replace "or" with "and" before the term "after surgery." Support for these amendments can be found in the specification and claims as originally filed. See, *e.g.* specification at page 13, lines 1-6.

Claims 1-12 and 14-17 are pending.

B. The Enablement Rejection is Moot

Claims 18-24 are rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. According to the Examiner, the specification allegedly "does not reasonably provide enablement for prevention of post surgical vomiting." Action at 2.

Applicant disagrees. Undue experimentation is not required to practice the subject matter of claims 18-24. However, in an effort to further the prosecution of this case and secure prompt allowance, claims 18-24 are canceled. Therefore, the enablement rejection is moot, and Applicant requests that it be withdrawn.

C. The Obviousness Rejections Are Overcome

1. The cited references fail to disclose or suggest Applicant's invention

Claims 1-7, 10-19, and 21-24 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent 6,340,695 to Gervais ("Gervais") in view of Apfel (PONV Research). Dependent claims 8, 9, and 20 are rejected as being obvious over these references in further view of Ansel *et*

al. Applicant will address both rejections with the same arguments. *See* MPEP § 2143.03 ("If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious.").

The pending claims are not rendered obvious over the cited references. For instance, Apfel does not appear to be prior art to Applicant's claimed invention, as it appears that the Examiner printed this reference from a website on February 4, 2007. However, even if Apfel is prior art, a *prima facie* case of obviousness does not exist as the combination of the cited references fails to disclose every element of the claimed invention. *See* MPEP § 2143 ("To establish a *prima facie* case of obviousness...the prior art reference (or references when combined) must teach or suggest all the claim limitations.").

By way of example, and in an effort to further the prosecution and secure prompt allowance, independent claim 1 has been revised to now recite:

> A method of reducing post-surgical vomiting in a patient comprising administering to the patient a therapeutically effective amount of Doxylamine Succinate and Pyridoxine Hydrochloride **before general anesthesia is administered to the patient and before the patient presents symptoms of post-surgical vomiting**.

Claim 1 (emphasis added).[1] At the very least, the emphasized language is not disclosed or suggested by any of the cited references.

Gervais generally teaches a rapid onset formulation comprising Doxylamine Succinate and Pyridoxine Hydrochloride as active ingredients and having specific *in-vitro* dissolution profiles, such formulation being useful in the treatment of nausea and vomiting. As noted by the Examiner, Gervais recites that "the formulation [...] may be used in the human and veterinary

[1] Non-limiting support for revised claim 1 can be found in the specification at page 13, lines 1-6. For instance, this passage clearly shows that the administration of Pyridoxine HCl and Doxylamine succinate begins before general anesthesia is administered to the patient and, thus, before the apparition of any post-surgical vomiting symptoms.

fields of medicine whenever ***symptoms*** of nausea and/or vomiting require medical intervention" (Gervais, column 2, lines 56-59) (emphasis added).

Thus, in Gervais, the formulation comprising doxylamine succinate and pyridoxine hydrochloride is used after some nausea and/or vomiting symptoms are present and require medical intervention, *i.e.*, on existing symptoms. Importantly, Gervais does not teach or suggest that the formulation of doxylamine succinate and pyridoxine hydrochloride is or should be used "before general anesthesia is administered to the patient and before the patient presents symptoms of post-surgical vomiting" as recited in instant claim 1. This is conceded by the Examiner. *See* Action at page 6 (explaining that Gervais "does not specifically teach 'reducing post-surgical vomiting'...comprising the administration before, during[,] after (at regular intervals), before anesthesia, on an outpatient basis, on an evening prior to, a morning of the day of and after surgery...."). *See* Action page 6.

As for Apfel, the Examiner cites this reference to "show that PNOV (postoperative nausea and vomiting) has been known in the prior art to be associated with general anesthesia." *Id.* at 7. This reference also fails to disclose Applicant's claimed method of administering "Doxylamine Succinate and Pyridoxine Hydrochloride before general anesthesia is administered to the patient and before the patient presents symptoms of post-surgical vomiting." If anything, Apfel emphasizes the importance of the problem solved by the present invention. The fact that Applicant solved this problem is strong evidence of non-obviousness. *See In re Dow Chemical Co.*, 837 F.2d 469 (Fed. Cir. 1988) ("Recognition of need, and difficulties encountered by those skilled in the field, are classical indicia of unobviousness.").

Turning to Ansel *et al.*, this reference discloses that delayed-release products usually are enteric coated tablets. There does not appear to be any teaching or suggestion of Applicant's claimed limitation of "before general anesthesia is administered to the patient and before the patient presents symptoms of post-surgical vomiting."

2. Conclusions concerning the non-obviousness of the claimed invention

The combination of Gervais with Apfel and/or Ansel *et al.* fails to disclose or suggest Applicant's claimed method of administering "Doxylamine Succinate and Pyridoxine Hydrochloride before general anesthesia is administered to the patient and before the patient presents symptoms of post-surgical vomiting." This is conceded by the Examiner at pages 6-7 of the Action ("[Gervais] does not specifically teach 'reducing post-surgical vomiting' comprising the administration before, during after (at regular intervals), before anesthesia, on an outpatient bases...") ("Anpfel is solely used to show that PONV...has been known in the prior art to be associated with general anesthesia.").

In addition, Applicant has provided detailed arguments and corresponding evidence of the existence of secondary considerations of non-obviousness (*e.g.*, surprising and unexpected results and satisfying a long-felt need). *See* Applicant's previous response of November 15, 2006, which is incorporated into this section by reference. Such secondary considerations confirm that the claimed invention is patentable over the cited references. *See* MPEP 2141 [I] (explaining the Graham factors).

For at least the reasons discussed above, Applicant respectfully requests that the obviousness rejections under 35 U.S.C. § 103(a) be withdrawn.

D. The Obviousness-Type Double Patenting Rejection Is Overcome

Claims 1-6, 13-18, and 19 are rejected for non-statutory obviousness-type double patenting as being unpatentable over claims 25-29 and 30 of U.S. Patent 6,340,695 in view of Apfel.

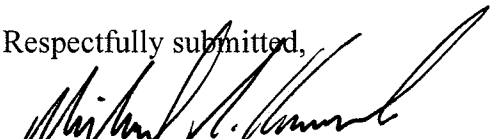
Applicant disagrees with the obviousness-type double patenting rejection. Because this rejection is based on the same references used to support the § 103(a) rejections, the arguments made above equally apply to this rejection and are incorporated by reference. Applicant requests that this rejection be withdrawn.

E. Conclusion

Applicant believes that this is a complete response to the Office Action mailed February 8, 2007. The present claims are in a condition for allowance, and such favorable action is requested.

The Examiner is invited to contact the undersigned Attorney at (512) 536-3030 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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